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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/776,431

02/02/2001

Jude S. Sauer

LS-002

5301

7590

05/28/2004

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EXAMINER

MUROMOTO JR, ROBERT H

ART UNIT

PAPER NUMBER

3765

DATE MAILED: 05/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/776,431

Applicant(s)

SAUER ET AL.

Examiner

Robert H Muromoto, Jr.

Art Unit

3765

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-32, 44-48, 73 and 74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 19-32, 44-48, 73 and 74 is/are rejected.
- 7) ☒ Claim(s) 8-18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 19-32, 44-48, 73 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swain et al. '153 and '730, in view of Yoon '731 and further in view of Ishikawa et al. US patent 6,071,233.

As recited in the background of the invention section of the instant specification, Swain '153, and '730, teach a sewing device coupled to the distal end of an endoscope, which enables suturing in the gastroesophagus tract; and a device for securing and cutting sutures using an endoscope. The teachings of Swain '153 and '730 provide all the functions and structure of the instant invention as recited in lines 3, pg. 2 – lines 1-8 pg. 3, of the instant specification. They do not teach a system in which the suturing and cutting functions are performed with one endoscopic device where the suturing and cutting channels are detachably connected at an outside portion of the endoscope.

However, Yoon, teaches a surgical instrument with multiple rotatably mounted end effectors that allow medical procedures that had previously used multiple insertions steps to be performed with only one insertion and therefore reducing the invasiveness and healing time for the patient. Yoon teaches an instrument for performing internal surgical procedures that includes a housing and a distal end with a periphery edge, a

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first end effector assembly protruding from the distal end and a second end effector assembly protruding from the distal end of an elongate shaft. A pair of collars 20a and 20b are disposed axially along the length of the shaft.

Fig. 4 shows the elongate shaft 16, which is of cylindrical configuration with a plurality of longitudinally extending passages or channels 22a, 22b, 22c, 22d, 22e.

**Channels 22a-e can alternately be formed by thin wall tubular sleeves** (inherently flexible) extending longitudinally through shaft 16. The shaft can be rigid or flexible and can be made of any suitable material, such as stainless steel or plastic. The end effectors 18a and 18b shown in figures as forceps, can be changed to any suitable surgical member for endoscopic procedures such as needle holders, staplers, scissors, clip applicators, etc. (col. 6, lines 52-590). The effectors 18 a, b, can also perform procedures such as suturing (col. 7, line 25-35).

The only difference from these combined teachings and the claimed invention is that the tube containing the different end effectors are internal with the endoscope while the claimed invention requires the tube be attachable at one or more locations along the outside of the endoscope shaft.

Ishikawa et al. '233 teaches an endoscope with an extra tube or channel 15 shown in figure 1, that is flexible and attached at 14 which is outside the endoscope channel which allows the outer tube 15 to flex with the endoscope as recited by claim 1.

Therefore at the time of invention to one of ordinary skill in the art it would have been obvious to combine the teachings of Swain et al. '153 and '730 to the teachings of Yoon in view of Ishikawa to provide an endoscopic suturing device which would put the

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suturing device, cutting device, or any other small surgical device for endoscopic procedures on the same apparatus to reduce the number of insertion steps in the suturing procedure which would decrease the invasiveness of the procedure and the healing time of the patient.

### ***Response to Arguments***

Applicant's arguments filed 8/1/2003 have been fully considered but they are not persuasive.

Applicant argues that the combined teachings do not teach a flexible tube. However, Yoon clearly states that the channels are "thin walled" tubes which are made of "stainless steel, or plastic" which would be flexible.

The combined teachings above are clearly within the same problem solving area of internal surgery with instruments.

Yoon provides numerous embodiments of different end effectors which could be included into a device which would reduce the invasiveness of internal surgeries. The examiner has combined Yoon with the teachings of Swain because the applicant has stated in the background that Swain teaches the limitations of the claimed invention except for the flexible tubes and the concept of using one insertion device which includes multiple flexible conduits for various surgical instruments to be used without the need for increased invasiveness of the surgical procedure. Clearly, Yoon has shown this inventive concept.

### ***Allowable Subject Matter***

Claims 8-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 8-18 recited specific structural limitations of a suturing instrument to be used with the device of the instant invention.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert H Muromoto, Jr. whose telephone number is 703-306-5503. The examiner can normally be reached on 8-530, M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Calvert can be reached on 703-305-1025. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bhm  
May 3, 2004

  
JOHN CALVERT  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700